

The Governance of European Intellectual Property Rights: Toward a Differentiated Community Approach

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Abstract

In this article we argue that the regulation of Intellectual Property (IP) protection should go beyond the traditional regulatory models and follow a more flexible regulatory framework. Considering the range of industrial needs and developments, the article develops a differentiated Community IP protection model that could stimulate growth and innovation, alter the behavior of patent users, and improve the quality of patents through spontaneous harmonization and convergence. To explain the model better, we distinguish two key elements: differentiated framework directives and epistemic patent communities. Differentiated framework directives dictate the establishment of general patentability standards at the EU level but allow national patent systems to set up stricter patent standards for particular subject matters at the national level. In this way, differentiated framework directives should lead to an appropriate balance between the principles of the IP protection regime and the ideals of economic integration. However, given the current diversity in innovation developments and industrial operations, we recognize the risk that not all IP stakeholders would agree to a differentiated Community IP protection model. To overcome the risk of deadlock within model negotiations, and to encourage the integration of countries that want to move forward and advance certain innovation developments, we propose the creation of epistemic patent communities. In this article, epistemic patent communities are perceived as strong mechanisms for establishing an inclusive patent protection environment that encourages various stakeholders to agree on certain patentability principles and to acquire better IP protection at the EU level.

Keywords: Intellectual Property (IP), Patent Systems, Innovation, Differentiated Integration and Framework Directives

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1. Introduction

The rationale for European intellectual property rights (IPRs) and particularly patents is that they should stimulate innovation among various stakeholders and contribute to its broad dissemination. The stimulation of growth and innovation relies on improving patentability standards and enhancing access to new inventions. As such, the establishment of an effective patent system is crucial. The effectiveness of an IP protection regime is determined by its ability to adapt to the needs of the knowledge-based economy¹, be equally accessible, and provide legal certainty (Pottelsberghe, 2009). Europe has tried to find a basis for an effective patent system through the European and the Community patent systems. Whereas the European patent system was established by the European Patent Convention (EPC), and governed by the European Patent Office (EPO), to establish a centralized patent granting process; the Community patent system was initiated by the European Commission to foster the long-term goal of creating a unified IP protection regime as part of a move toward an undifferentiated, one-size-fits-all IP protection regime throughout the EU.

Within the European patent system, the regulation of patentability issues has followed the traditional territorial principle in which national authorities are free to determine the scope and the interpretation of patents. Even though the European patent system has led to uniform patent granting conditions, the substantive terms of protection (the interpretation of the patentability standards and the enforcement of patents) fall under the authority of the national patent systems, which are similar but not identical across the EU (Piotraut, 2004; Ullrich, 2006). For an invention to be granted a patent it should be new at the time of patent filing (i.e. novel), involve an inventive step that is not obvious to a person skilled in the art (non-obviousness), and generate useful outcomes (industrial applicability) (Langinier and Moschini, 2002; Tödtling and Trippel, 2005). In addition to these standard requirements, patent examiners also have to determine the extent to which a particular subject matter is patentable. However, since National Patent Offices (NPOs) have failed to come to a mutual recognition and application of these concepts, the EPO's Contracting States² continue to apply divergent patentability rules that have resulted in patents of unequal values, dubious quality, and high levels of legal uncertainty.

¹ A knowledge-based economy is characterized by high degrees of industrial, socio-political, and national diversity.

² Currently, the EPO has 36 Contracting States, including 27 EU Member States.

Conversely, the proposed Community patent regulation emphasizes that the main purpose of the system is to contribute to realizing a single market and a common IP protection regime, with a unified patent throughout the Union that will be granted, regulated, and allowed to fall only in respect of the whole Union (Ullrich, 2002; 2006). Moreover, the Community patent system opts for a patent law that could be applied to any new technology. The IP protection principles behind this proposal have created many controversies within EU Member States (both industrialized and less developed countries). Since countries differ in their income levels, innovation preferences, and abilities to secure appropriate innovation and technological investments, it is difficult for them to agree on a unified approach to IP protection. They fear that such an approach might lead to a monolithic and centralized system that would discourage inputs from certain technology experts and industry leaders, and might be optimized only for some industries that would benefit the most.

Recent industrial and technological developments (such as in the fields of biotechnology and computer software) have dramatically impacted on the growth of patent applications and on the debate over IPRs. This reflects the inability of the granting agencies and patent examiners to apply existing patentability standards to these innovative dynamics. While IP protection legislators provide the basic patentability standards that countries need to follow, they fail to adopt them to the new industrial needs. Recent developments in innovation highlight the fact that new patentability issues (e.g. scientific inventions) and actors (i.e. research institutions, universities) have entered the patentability area, and that these challenge the applicability of the existing standards. Since some inventions are the result of cumulative scientific work (e.g. the science-based, pharmaceutical-related inventions) they do not fit easily within the traditional patentability standards and regulatory frameworks that have been applied to other subjects. Science-based inventions are developing faster than Community legislation and show the need to improve both the governance and the regulatory framework of the existing IP protection regimes, while providing a more inclusive environment that recognizes the contributions of various stakeholders and experts.

The regulatory framework and the governance of IPRs within Europe remain crucial to the innovation policy because they provide the basis as to whether a particular subject matter is patentable, and determine the boundaries (the products and the processes) in which patent holders can exercise their patent rights. Moreover, an understanding of the IP protection regulatory framework and governance provide incentives for patent examiners to adapt the IP regimes to the patenting trends in various fields and sectors. Political scientists approach the concept of regulatory

frameworks, and particularly the concept of governance, from different points of views: as a regulatory approach, an actor-based approach, or as an institutional approach (Borrás, 2003; 2006). These approaches coincide with the principles behind the traditional governance model according to which the regulatory policy frameworks are established by political communities that are constituted on the basis of specific political institutions at national or sub-national level, and governance is perceived as a concept of command and control by the state. This article goes beyond the traditional regulatory models and follows a more flexible understanding of IP protection regimes. We would argue that since patents reflect the existence of a system that operates at the public-private divide³, the regulatory framework of these IPRs needs to go beyond the formal rules of regulation, and focus on the effective inclusion of different systems, stakeholders, networks, and market interactions among the public and private sectors. Such an approach would lead to a hybrid regime that is collectively enacted within the society.

As noted earlier, within the area of IPRs, the EU has continuously tried to establish a uniform regime built upon common regulations. However, the inability of the Community to achieve a collective agreement and understanding of IP protection principles has led the issue of the EU patentability regulatory framework to an impasse. As a result, many issues remain unresolved, such as: how new technological developments can be incorporated within the existing IP protection regulatory frameworks in Europe; to what extent should Contracting States be able to control the operations of the patent standards within their territories; how to establish an inclusive IP protection regime that would balance the tasks between the Contracting States and the EU. By focusing on the evolution of the regulatory framework for IPRs, and specifically on patents, this article examines these questions in detail, and proposes a more flexible, sector-specific patent regime that would build upon differentiated adjustment strategies. A regime that would stimulate both growth and innovation, while bringing together experts from various fields to clarify the mission of the IP protection regime and improve the quality of patents through natural harmonization and convergence. The article is organized as follows. The next section highlights the main factors that affect the ability of the European patent system to provide an appropriate basis for IP protection and innovation development. Section 3 explains the principles of the Community patent regime and discusses its potential consequences for IPRs. Section 4 elaborates on a differentiated Community IP protection

³ Since patents are granted by state authorities, they become part of the public legal system, but the granted patents emphasize an industrial entitlement - a property right, and this has implications in civil law. However, patents are enforced by public jurisdiction through the courts.

model and on the impact that its components have on establishing an effective IP protection regime. The final section summarizes the findings and draws some conclusions.

2. Re-considering the Role of the IP Protection at the European Level

The initiatives toward the establishment of an IP protection regime at the European level were finalized in the Munich Convention of 1973. During the 1970s, the EPC established the EPO as an alternative⁴ through which countries could acquire IP protection (Piotraut, 2004). The political goal of this intergovernmental regime was to establish a uniform patent system but, in reality, it only managed to establish a centralized patent granting process, while the resulting process and the legislative authority for the use of patents remained under the national jurisdictions of the Contracting States. A single application to the EPO, after a standard examination procedure, results in patents being granted for whichever countries the applicant asks and pays for. The centralized granting procedure has facilitated the management of patent protection policies, but applicants are still required to pay national maintenance fees for all the territories to be covered, which results in high costs for the applicant (Harhoff and Reitzig, 2004). A patent granted by the EPO is typically validated for five or six countries. It is important to note that the granted rights do not represent a unitary European patent, but a bundle of national patents. The national jurisdictions retain the power to reject patent rights even when the EPO has granted the patent, and conversely national countries can uphold a patent application in their own territory even if the EPO has rejected it. In this way, the current institutional setting of the European patent system divides the market into areas where a patent is enforced and those in which it is not. This creates high levels of legal uncertainty and low-quality patent granting system that could lead to segregation in the operation of the internal market (Wiebe, 2000), contrary to the provisions of Article 95 of the EC Treaty⁵.

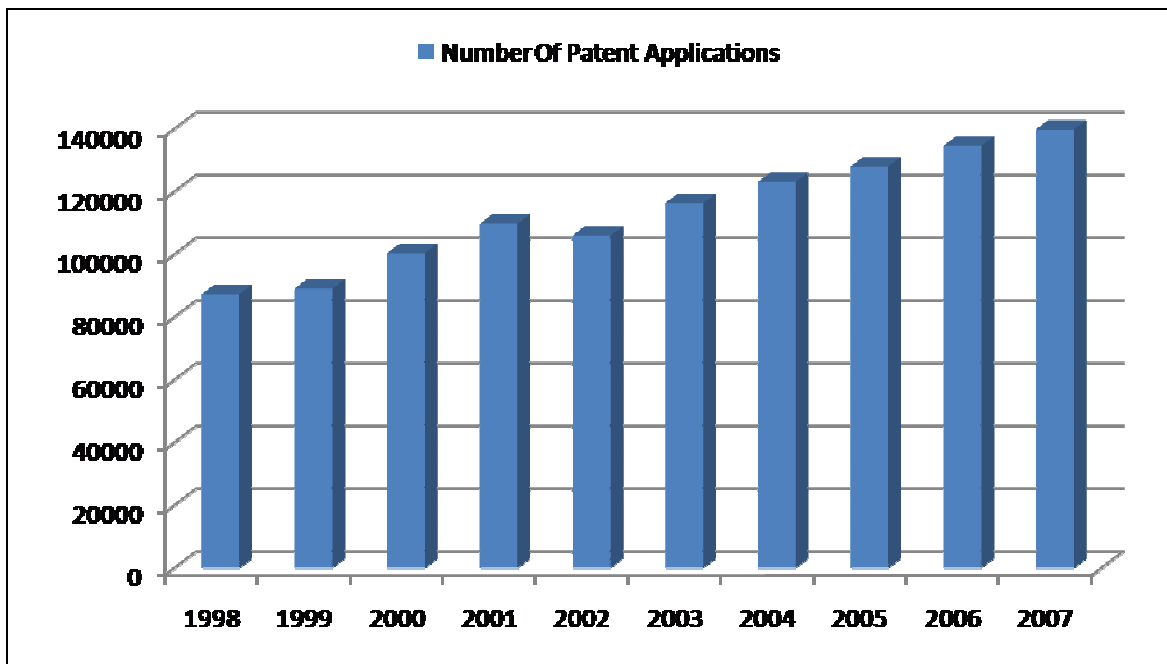
Nevertheless, despite the deficiencies within the European patent system, there has been an increase in the number of patent applications to the EPO reflecting the growing impact of this intergovernmental organization in the IP protection field. The number of patents filed within the EPO has grown from 82,261 in 1997 to 140,725 in 2007 (see Figure 1) and, significantly, half of these come from the IT and the biotechnology industries. When comparing the scale of the patents with those of a decade ago, it is clear that today's patent applications are much broader and include more

⁴ The European patent system is not exclusive; applicants can also obtain strictly national patents if they are only interested in obtaining patent protection in one or a few of the EPC Contracting States.

⁵ Article 95 of the EC Treaty provides for the adoption of the Community-wide rules that reduce barriers to trade and market entry among Member States, and improve the functioning of the single market.

claims⁶ with less specific content. Since the 1980s, the size of patent applications to the EPO has more than doubled (in the 1980s a patent typically included 10 claims, while the average is now 22 claims) (Mejer and Pottelsberghe, 2009).

Figure 1: The European patent applications of the EPO member states 1998-2007

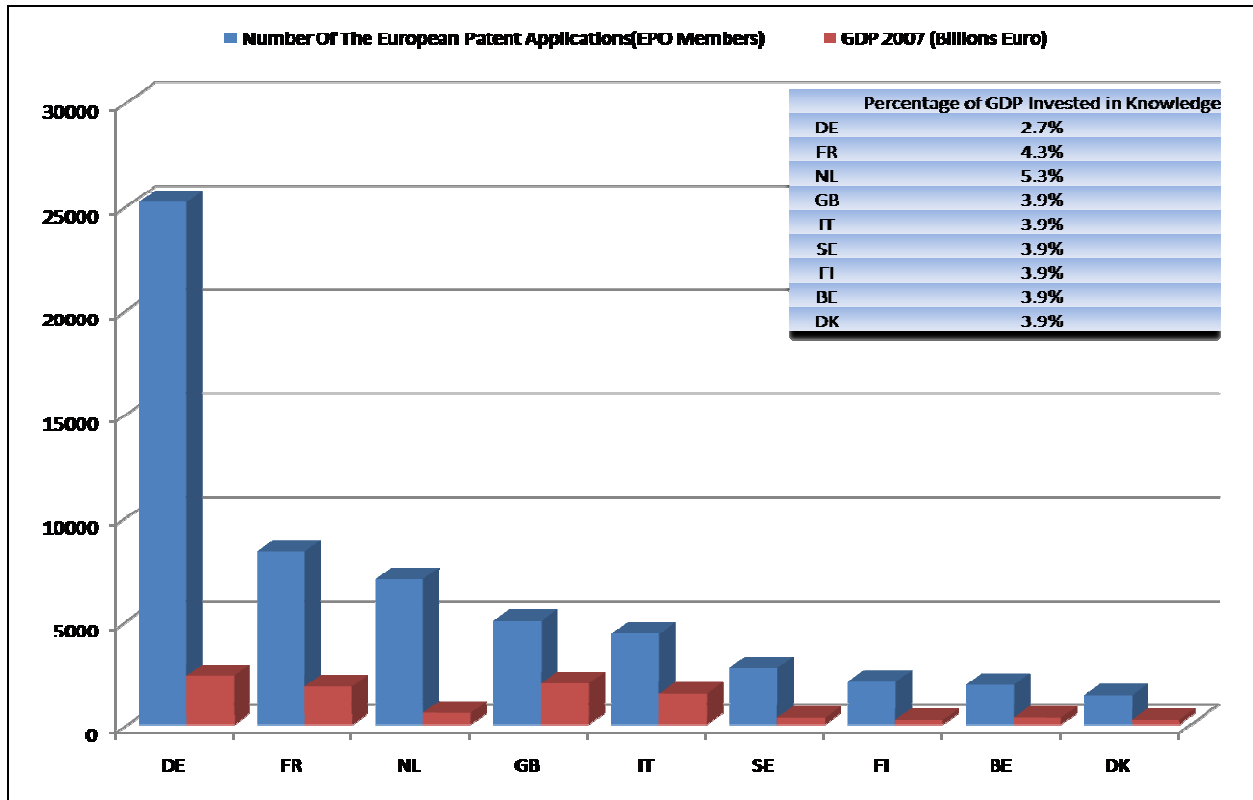


Source: The EPO Database. European patents and patent applications;
Available at: <http://www.epo.org/about-us/office/statistics.html>

The increasing number of patent applications does to an extent reflect the success of the EPO, but it also implies that countries, or rather their leading market actors (large companies, SMEs, individual inventors, etc.), are much more involved in protecting their property. These patenting trends have been influenced by national economic capacities (GDP), national investments in knowledge, and national capabilities to adapt to the changing innovation environment (Cowan, Eijk, Lissoni, Lotz, Overwalle and Schovsbo, 2006; Tsipouri, Reid and Miedzinski, 2008). As illustrated in Figure 2, countries with higher GDPs and which invest more in knowledge (make higher inputs on innovation) are more likely to have larger innovation outputs and a relatively large number of patent applications.

⁶ Patent claims emphasize the products or processes that the inventor aims to cover in the protection conferred by the patent. Usually the patentee aims to claim as much as possible in order to ensure a monopoly situation in the market.

Figure 2: European patent applications in the most prominent countries⁷ within Europe



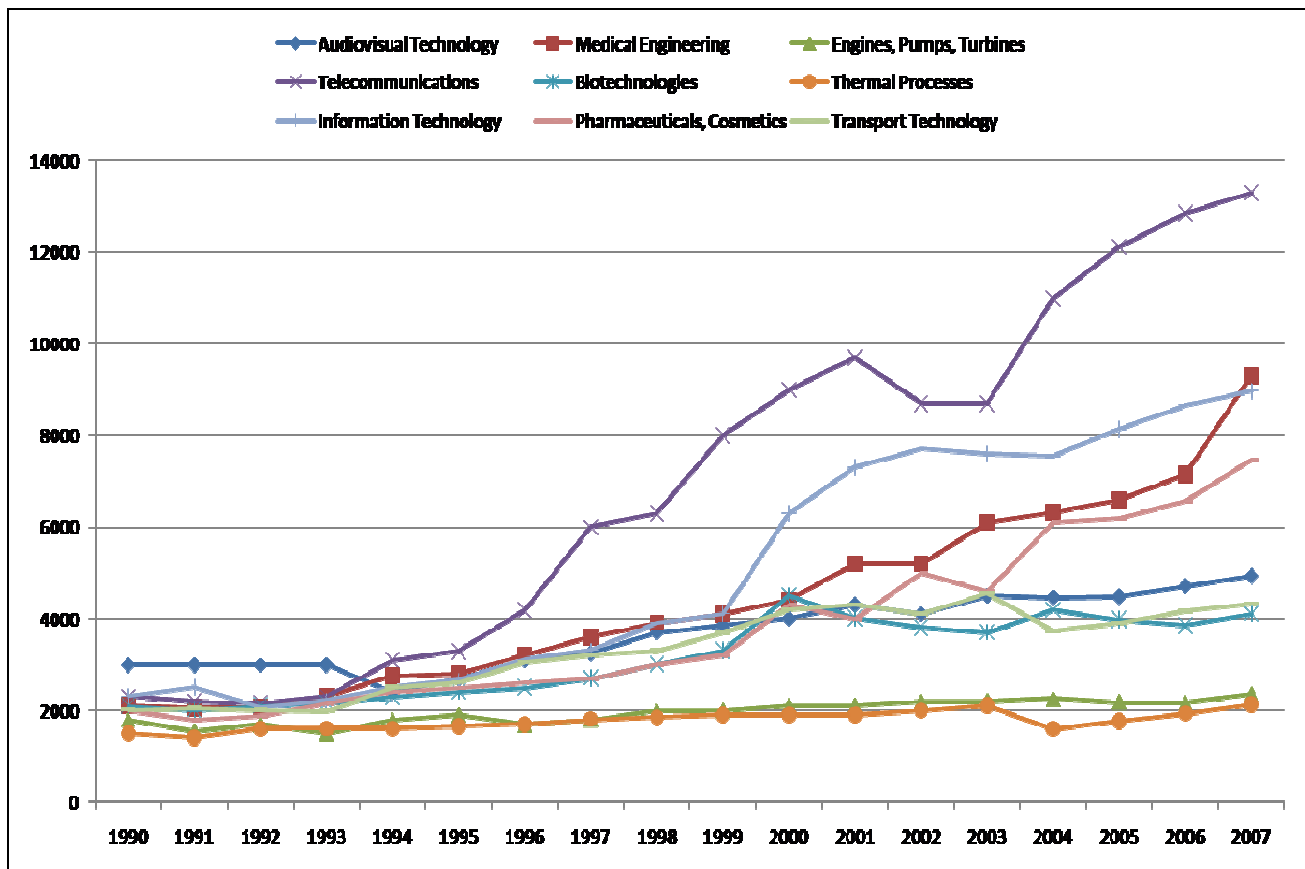
Source: The EPO annual reports. European patents and patent applications;
Available at <http://www.epo.org/about-us/office/statistics.html>

In addition, the striking growth in the number of patents over the last decade shows how innovation processes have become more competitive and dependent on the new high-tech firms, and on research institutions and networks, and how the access of new types of institutions⁸ in the patent arena (e.g. universities) has remarkably impacted on the development of new subject areas (such as science-based, pharmaceutical-related inventions). Among the fastest growing technologies are ones within the electrical engineering and electronics (IT, telecommunications, audiovisuals), pharmaceutical and biotechnology fields, and medical engineering (see Figure 3). The rapid growth of these technologies reflects their high potential to modernize Europe's industrial base and its share of the global high-tech market. The EPO Database indicates that, by 2001, the market for software had reached €60 billion, and in biotechnology it is expected that investments may exceed €2000 billion.

⁷ The EU Member States (and EPO Members) with the highest number of patent applications within Europe.

⁸ In the 1980s, only 0.5% of all applications came from academia, today the figure exceeds 4% and about 5000 applications are filed each year at the EPO.

Figure 3: The European patent application of the EPO member states per technical field 1990-2007



Source: The EPO annual reports; and the Scientific Technology Options Assessment Report, 2006 ⁹

Recognition of the above mentioned patenting trends is of crucial importance because they question the ability of the European patent system to provide an appropriate regulatory framework that effectively responds to these new technological developments. The EPC provisions do not provide any guidance as to when an item can be considered an invention, although Article 52 (2) does include non-exhaustive list of what should *not* be considered an invention¹⁰ (Freedman, 2000; Kranakis, 2007). This creates many dilemmas within countries and industries as to the patentability of new technologies (e.g. biotechnological products, computer software, integrated circuits, information

⁹ See: Cowan, Robin., Eijk, V. Wim., Lissoni, Francesco., Lotz, Peter., Overwalle, V. Geertrui & Schovsbo, Jens. (2006). *Policy options for the improvement of the European patent system*. (STOA/FWC/2005-28). Brussels: Directorate General for Internal Policies; and <http://www.epo.org/about-us/publications/general-information/facts-figures>

¹⁰ Article 52 (2) of the EPC states : “ It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of : a) a discovery, scientific theory or mathematical method; b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever; c) scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer; d) the presentation of information”

technology). Since patenting dynamics are mostly led by “science-based” or “complex” technologies, they challenge the European law and the applicability of current patent standards within the European patent system, and have created a need for EU legislation to contribute more to meeting the new industrial needs and to the mutual understanding of IP protection across countries.

In line with Article 52 (1) of the EPC Treaty, the EPO grants patents for all types of products and processes provided they are non-obvious, novel, involve an inventive step, are susceptible to industrial applicability, and have a technical character (Borrás, 2003). These criteria set the basic patentability standards that countries are supposed to follow, but they have failed to adapt to the new technological developments that challenge the applicability of these standards. Moreover, since the EPC Article does not specify exactly what constitutes an invention, it leaves considerable leeway for the Contracting States to determine what is considered an invention, and this has created many disputes at national courts as to the correct interpretation of the EPC patent provisions (Heath, 2002; Begley, 2007). Several court cases (including *Epilady v. Remington*; *Angiotech v. Conor*) reflect that discrepancies in interpreting a common set of standards applied for granting a patent to an invention have led to an increase in legal uncertainty among countries, and to poor quality patents¹¹.

It is important to note that many of the new technological developments have made the approach of developing general patentability standards unworkable because some industries have advanced to the point where they can satisfy the established standards for being granted a patent, while still leading to later disputes. For example, today’s software programs are mostly an accumulation of existing programs, which might serve not only the purpose of immediate commercialization, but might also be used for future research. In this way, software developers use various pieces of existing programs to develop new software tools (Cohen and Lemley, 2001; Panagopoulos, 2003). While a new assemblage of software pieces might fail to meet the patentability standards due to a lack of novelty, it is difficult to determine the state of the art because such ‘inventions’ are not documented in journal articles or papers. As such, a new assemblage might pass the novelty test and, if the components are not recognized by the skilled programmers involved in its assessment, the new program might well pass the inventive-step test. Although, such a granted patent could be revoked, this would

¹¹ According to the European Patent Conference (EUPACO) in Brussels, a quality patent should: a) involve a highly inventive step, b) be clearly written, and c) be carefully examined by the patent examiners during the examination stage. Patent examiners should be able to access the literature as well as various scientific publications (i.e. prior art) that are related to the invention. More information available at <http://www.eupaco.org/eupaco2>

undoubtedly take time, and involve large costs in obtaining expert advice and evidence and then in applying for a formal revocation.

Recognizing the complex actions that companies or countries might take when ‘imitating’ computer and software inventions, large manufacturers (who are mostly behind such inventions) opt for strong patent regimes with lengthy broad patents (Frischtak, 1995). Moreover, to recoup their innovation costs, these manufacturers use their inventions as bargaining devices or as threats in cross-licensing or infringement cases, and aim to patent each sub-invention that has the potential to enter their complex systems (Borrás, 2003; Hall, 2007). This has led to an explosion of patent applications in electronics and other complex technologies, and to patent overlap, as well as to disputes between large companies and other social groups (such as SMEs). While large companies opt for a strong patent regime, the other groups argue that, since the generation of “essential patents” is easy but costly in this sector, software patenting might lead to an anti-competitive effect that might block the development of smaller enterprises. The controversies and disputes among these actors led to the failure of the proposed EU Software Directive which set out to regulate the protection of these inventions at the EU level and to determine the terms and the eligibility criteria for software patents.

Alongside software inventions, the biotechnology sector is also worth examining since it shows the impact that various IP disputes have had in making this industry one of the few sectors in which EU legislation has managed to harmonize the protection of inventions at the EU level. Before the advent of biotechnology, the patenting of higher life forms was seen as unacceptable. Moreover, Article 53 (b) of the EPC specifically ruled out patentability of transgenic animal and plant varieties. The EPC Articles were disputed during the ‘Harvard mouse’¹² (which concerned a transgenic mouse - a non-human animal susceptible to cancer) and the PGS cases (which sought a patent on a transgenic plant invention) (Harhoff and Reitzig, 2004). In the first case, the EPO Board of Appeal granted a patent and accepted the invention on the basis of Article 53 (a) and (b), while the Board denied a patent in the second case on the basis of Article 53 (b) interpreting the PGS plant as an unpatentable “plant variety”. These decisions led to many disputes among the parties because the Board could not give any logical explanation for its application of the patentability standards and strategies (i.e. why in the

¹² Initially, the EPO Board of Appeal refused to patent this invention, excluding it as an “animal variety” on the basis of Article 53 (b) although, when considering Article 53 (a), the EPO Board of Appeal was unable to determine whether this invention violated public policy. This decision was appealed, and the Board of Appeal then held that Article 53 (b) excluded “animal varieties” from patentability but not animals. As such, the EPO then granted its first patents for a transgenic non-human animal. Following this case, Plant Genetic Systems also sought a patent on a transgenic plant. The EPO granted the patent, but this was immediately opposed by Greenpeace. Following this opposition, the EPO re-examined this patent application and rejected it under Article 53 (b) as an “unpatentable” plant variety.

first case a patent for a transgenic ‘invention’ was granted and in the second case denied)¹³. Moreover, it emphasized the need for the EU legislation to intervene in democratizing the governance of patents and to expand the regulatory framework of IP protection from regulating only the “classical” biotechnological matters (e.g. food technology, microbial treatment of sewage water, etc.) to establishing appropriate regulatory frameworks for specific issues within the field (i.e. new plant and animal varieties). As a result, the European Commission adopted a Biotechnology Directive which provided sufficient legal protection for biotech inventions, while strengthening and harmonizing European patent law in this industry through a secondary EU law.

In this way, the biotech industry is among the few sectors in which patents are regulated at the EU level and are validated in all 36 Contracting Countries. However, the issue of gene patents remains unclear within this industry. Generally, genes are considered to be part of our “common human heritage” and that patenting them would contravene public order and morality. However, since the EPC does not define the meaning of the public order, nor specify what types of subject matter contradict public morality, some countries have issued gene-related patents¹⁴, which are very broad in their nature and it is argued risk blocking further scientific progress (Freedman, 2000; Williamson, 2001).

Besides the lack of clarity on standards and requirements for the patentability of new subject matters, the lack of collaboration among the NPOs and the European patent examiners, plus the workloads associated with patent examinations, have contributed significantly to the inability of the system to accommodate the widening diversity in subject matters. In establishing a centralized patent-granting system, the national patent systems effectively acted as centrifugal forces in shaping the function of the EPO and consequently benefited from its provisions. However in the later years of its operation, the EPO has established examination procedures for multi-territorial patents and acquired all the competences related to registering and examining patent applications. This has reduced the impact of the NPOs, as registration and examination systems, and relegated them to purely domestic market offices mostly responsible for post-grant patent issues (Ullrich, 2006; Kranakis, 2007). All of this has created a gap in the collaboration among European patent examiners, NPOs, and national

¹³ In general, these problems stem from the fact that within the EPC there is a lack of a clear definition of plant and animal varieties. For example, the term “animal varieties” is found in the English text, but the German text translates to “animal species” and the French to “animal breeding”. These terms describe distinctly different animal groupings and this creates enormous obstacles within the European biotechnology plant industry.

¹⁴ In 1983, France patented an isolated yeast. Patents have also been issued in respect to a gene sequence for a hepatitis B antigen, and for vitamin B12.

experts/stakeholders, and limits the opportunities for patent examiners to get thorough the information on an innovation's novelty and state of the art, and to then conduct an effective patent examination and enforcement process. As a result, patent examiners end up granting low-quality patents (i.e. patents that would not have been approved had the examiner thoroughly considered the relevant prior art of the invention) or refusing valid applications.

The above discussed issues within the European patent system and the parallel technological developments show that the actual IP protection regime has succeeded to some extent in providing a centralized patent-granting system but that it has failed to provide a regime that leads to an inclusive and effective IP protection environment. Acknowledging the deficiencies of the current IP protection regime, the European Commission has reintroduced the idea of a Community patent system. Since such a regime has been constantly proposed and rejected¹⁵, its proposed re-establishment raises many questions within the IP arena, including the crucial dilemma as to whether the proposed principles of this regime would provide a better way to protect and develop innovations in various fields.

3. Assessing the Role of the Community Patent Regime

As outlined in the previous section, the current IP protection system features the coexistence of national and European patenting systems. Adding the Community patent to these options could result in patents with a unitary character (valid in all EU Member States), which would be granted only in respect of the whole Union. As such, the system might lead to lower maintenance fees, better opportunities for an integrated European market, and lower translation costs (if an appropriate translation framework is established)¹⁶. The Community patent system is seen as an alternative patent protection route to the existing system, and countries would be free to choose between the European and the Community patent when the EPO was deciding whether to grant a patent (Ullrich, 2002; 2006). Nevertheless, the Community patent regime has often been controversial in principle because, within this proposal, the EPC remains responsible for setting the conditions for granting the Community patent, and the EPO for receiving, examining, and deciding patent granting issues. Besides this, the Commission has proposed the establishment of a centralized Community Patent

¹⁵ The EU has had the idea of a Community patent since 1975. However, disagreements among the Member States about the provisions of the Community Patent Convention (CPC) led to this proposal being frequently relaunched and never entirely accepted by the Contracting States. In 1997, the Commission passed a Green Paper on Innovation, in which the establishment of a Community patent was a priority. Following this initiative, in 2000, debates over a uniform IP protection regime captured the attention of many politicians and policymakers, but a common agreement has yet to be achieved (Heath, 2002).

¹⁶ The proposed Community patent required patent claims to be translated in their entirety into all languages of the Member States, which would obviously be extremely expensive and impractical in terms of efficient operation of the system.

Court with exclusive jurisdiction over validity and infringement matters but not, however, in matters concerning contractual or compulsory licenses (Begley, 2007). In this way, there would remain a split in jurisdictions: the Community Patent Court would have jurisdiction only for post-patent-granting litigation matters, whereas litigation over the granting, limitations and revocation of Community patents would remain within the EPO's jurisdiction.

The disputes over the Community patent regime basically come down to its inability to provide flexible IP protection that accommodates the needs of diverse industries and concerns over the capacity of the Contracting States to adopt and transpose the Community IP protection principles to the national level. An initial concern is that the basic idea of the Community patent regime, to establish a unified patent system whose principles will be valid to all technologies with no need for technology or industrial specifications, risks the establishment of a monolithic centralized system which could only be changed if the "inner leaders" (aggregated from the entire business spectrum) indicated that a change was needed (OECD, 2006). The fear is that this could discourage inputs from technology experts and industry stakeholders because their perspectives would be limited to isolated vertical segments and not be of sufficient weight to invoke changes. The danger of the one-size-fits-all regime is that it might end up being optimized only for those industries that potentially benefit the most, because they would put the most effort into the operation and evolution of the system. Taking into account the fact that the pharmaceutical and chemical industries are involved in the protection of drugs worth billions of dollars, it is natural that these industrial sectors will make a strong input in shaping IP protection principles. Therefore, a one-size-fits-all IP regime might end up biased toward the needs of these industries and, as a consequence, over- or under-protect other technological sectors, and fail to fully account for other factors that might be relevant for optimal levels of protection.

As noted earlier, patenting trends have changed drastically, and the ability of an industry or a country to foster innovation and technology development now depends on many variables, each of which requires specific attention. Industries differ in the way they process innovations and in their application of patentability standards. Some innovations tend to be relatively isolated and others rely more on the continuous innovation process (Cohen and Lemley, 2001; Encaoua, Guellec and Martínez, 2006). For example, the pharmaceutical sector is characterized by a relatively self-contained innovation process, one that generates a single finished product with few incentives for further improvement (i.e. once drugs are produced and tested, few initiatives are taken to improve

them). In such industries, the rate of new innovative ideas is usually low and the strong application of certain patentability standards (such as non-obviousness) might discourage innovation development because firms would have great difficulties in accessing the knowledge to which their competitors hold the patents. However, the situation may well be different in other industries (such as computer software and bio-informatics) where new innovative ideas are frequent and the application of certain patentability standards (i.e. novelty and non-obviousness) will need to be stronger. In this sort of industry, cumulative innovation is crucial because inventions cannot be developed without accessing the knowledge embedded in the previous generation of inventions. Therefore, patentability standards need to be strongly applied if one is to create incentives for R&D to innovate by ensuring higher turnovers for innovators (Langinier and Moschini, 2002; Tödtling and Trippl, 2005). These industrial differences are clearly inconsistent with the assumption that a uniform patent system will inevitably be superior.

Another issue with the Community patent system is that this regime might create disputes between countries that have large differences in the structural IP protection in their systems. Unlike the European patent system, once a Draft Regulation on Community Patent is adopted, it will automatically be part of the *acquis communautaire* and will not be renegotiated or amended in respect of new members. This might lead to fierce opposition in countries where such a regime would require major changes in the structure and the core functions of the national innovation systems (NIS). Recalling the data shown in Figures 1, 2, and 3, we see that there are huge differences among national preferences and industrial evolutions, which implies that different factors impinge on the success of NIS. Four types of Contracting States are distinguished in terms of the innovation process: the innovation leaders¹⁷, the innovation followers¹⁸, the moderate innovators¹⁹, and the catching-up countries²⁰ (Tsipouri, Reid and Miedzinski, 2008). Each group differs in its regulatory frameworks and social capacities, as well as in its abilities to secure appropriate financial investments in innovation. Among the important factors that challenge the ability of the policymakers across these countries to uniformly establish effective innovation systems within a reasonable period of time are capability, network, institutional and framework failures.

The capability failures reflect the inabilities of countries or industries to perform successfully due to managerial deficiencies and inabilities to understand, learn, and absorb new technologies. The

¹⁷ Switzerland, Germany, Denmark, United Kingdom, Sweden and Finland

¹⁸ France, the Netherlands, Austria, Belgium, Ireland and Luxembourg

¹⁹ Italy, Norway, Portugal, Iceland, Greece, Cyprus, Czech Republic, Estonia, Slovenia and Spain

²⁰ Bulgaria, Croatia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia

institutional and the framework failures emphasize the institutional inadequacies and the shortcomings that countries have within their IPR regulatory frameworks, innovation governance, and health and safety rules (Arnold, 2004: 7). These problems occur most commonly in the catching-up countries and the moderate countries that lack the administrative capacities to coordinate the use of knowledge, to provide incentive systems, and to follow the innovation routines of the more developed countries. Network failures occur due to the inability of actors within the innovation system to interact with and engage in knowledge generation and diffusion. Such failures are more common in the innovation leaders and the innovation followers that are usually locked-in to particular technological regimes or innovation systems, which prevent transition away from the traditional technologies and the complex interlocking systems (i.e. complex scientific knowledge, long-run cumulative development, complex engineering practices, and process technologies) (Smith, 2000). These failures reflect the complex challenges that policymakers face to ensure that the NIS perform as a whole. Therefore, it is hard to see how uniform one-size-fits-all regime would be superior in addressing the various needs and challenges. The above mentioned issues will present an obstacle if Contracting States try to rapidly change their national policy regimes and harmonize their national patent laws.

For all these reasons, since neither the European nor the Community patent systems have managed to ensure an effective IP regime (which would require constitutional equality of IP protection) or an inclusive innovation environment at the European level (that would require the harmonization of national patent systems), the regulation of IP protection remains in an impasse. Despite this somewhat gloomy story, this article aims to do more than elaborate only on the obstacles presented by the existing regimes. The object is to learn and move forward within the IP protection area by suggesting a more integrated and flexible patent regime. As such, in the next section, we propose establishing a differentiated Community IP protection model that builds on differentiated framework directives and epistemic patent communities to stimulate growth and innovation, to alter the behavior of patent users, and to improve the quality of patents through spontaneous harmonization and convergence.

4. A Case for a Flexible Intellectual Property Protection Model: The Differentiated Approach

In the present debate on the Community regulatory framework, the assertion of a legitimate diversity is often misunderstood as a demand for limiting European competences or as a process that needs to refer to examples of political diversity in which the principle of “subsidiary” has played a crucial

role. However, with the present state of economic integration, competition, and innovation development, the aspirations for a *Europe of Knowledge and Innovation* cannot be realized through purely national solutions. What is needed is an IP protection regime that is both flexible and Europeanized, and that provides an appropriate balance between the principles of the IP protection regime and the ideals of economic integration. On the one hand, a Europeanized IP protection regime should ensure a horizontal relationship among the national patent systems and knowledge subsystems²¹, as such providing a legal counterweight to the supremacy of the internal market, the European competition law, and regional knowledge diffusion. However, on the other hand, a Europeanized IP protection regime should play a crucial role in vertical coordination between the national and the European policy hierarchies. As such, it must ensure constitutional equality at the Community level for IP protection, and create incentives for the individual EU Member States to adjust their IP regimes to the competitive pressures of the internal market and to knowledge development.

Having considered the present situation within the IP protection arena, there is no doubt that a regime that ensures effective horizontal and vertical relationships is needed. However, the divergent patentability of the various subject matters and the normative aspirations of countries impact on the regulatory IP framework to such an extent that they defy the aspirations of uniform treatment in Community patent protection. Technological changes and innovation developments move faster than the Community legislator and the European patent legislature (Ullrich, 2006: 38), and imply a need for the system to ensure that national countries have a margin for experimental maneuver so that they can cope with local IP protection needs. Since the European and the Community patent systems have been unsuccessful in delivering such a regime, it is important to look at other options that might lead toward the goal of a differentiated and Europeanized IP protection regime.

Politically, the easiest way would seem to be through an amendment to EPC Articles 52 and 53 that would extend the minimum standards for patentability to cover new subject matters and the modernization of IP protection systems. However, since these requirements would lead to policy changes that would have to be accepted by all Member States, they might create controversies (for example, the innovation leaders might not find the amendment proposals as beneficial as the catching-up countries, or vice versa) and might fail to provide much legal protection for the cumulative innovations that are constantly evolving, and are used in the R&D process to stimulate

²¹ Knowledge subsystems usually comprise various national companies, consumers, suppliers, clients, and industrial cooperation partners.

further innovation (Langinier and Moschini, 2002: 12). Perhaps this situation could be avoided if the patentability authorizations were formulated more broadly, allowing directives to set up differentiated standards for regulating various patentable subject matters that take into account national innovation capacities, institutional developments, and economic abilities to pay at different stages of economic development in determining the level of IP protection.

4.1. Differentiated Framework Directives and the Regulation of Various Patentable Subject Matters

Within the course of European integration, the impact of directives has been dramatically increasing. Unlike regulations which become simultaneously binding on all Member States, directives give national governments discretion to determine the methods and forms employed to achieve the policy goals (Scharpf, 2002). As such, these legislative acts serve as a catalyst to encourage states to adopt a more integrated approach in establishing and implementing certain patentability principles or standards. The greatest advantage of these legislative acts in the IP protection area is that they do not apply to all Member States directly, but are binding only to the Member States to which they are addressed²². Therefore, they create opportunities for different groups of Member States to adopt substantively differing directives for different innovation subject-matters. However, since the national legislatures would always have to transpose these directives to their systems using different forms and methods, Member States will have an opportunity to adjust their patent systems through spontaneous harmonization. The regulation of patentability standards through directives has already occurred within the area of IPRs. For example, the Biotechnology Directive has managed to harmonize patentability standards in the biotechnology sector and has provided comprehensive access to legal protection for such inventions and to the market requirements (Wiebe, 2000).

Initially, this Directive created many controversies among Member States, since they could not agree on the scope of patentable subject matters²³. However, the rapid growth of the biotechnology industry induced the national legislatures and the courts to accept the protection of many biotechnological issues (i.e. for genetically engineered plants, animals, bacteria, and other life

²² Article 189 - EC Treaty states that: "A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods"

²³ The European Parliament rejected the original proposed Directive in its first legislative process because of the ethical issues related to the patentability of living matter. However, after ten years of intense debates among EU government institutions and citizen groups, and many amendments and drafts, the European Parliament and the Council enacted a Directive on the legal protection of biotechnology inventions within the EU (98/44/EC). For more information see: Kranakis, Eda. (2007). Patents and Power: European Patent-System Integration in the Context of Globalization. *Technology and Culture*, 48 (4), 689-728; and Begley, J.Kerry. (2007). Multinational Patent Enforcement: What the "Parochial" United States Can Learn from Past and Present European Initiatives. *Cornell International Law Journal*, 40, 522-570.

forms), and to finally adopt the Biotechnology Directive in 2007. It is important to note that even though the Contracting States accepted the Directive, disputes over the patentability of some subjects (e.g. human genes) remained, and some countries opted out on the patentability of certain matters (Cristoph, 2006). For example, Germany fulfilled the general requirements of the Biotechnology Directive by transposing most parts of it into its own legislative framework, but at the same time it enacted stricter national patentability standards for human genes²⁴. This example emphasizes that the Biotechnology Directive has promoted some general patentability standards established at the EU level (which has led to considerable convergence among Member States in terms of patentable subject matters) while still allowing some national diversity. As such, it is a clear case of a differentiated framework directive.

Following the example of the biotechnology industry, it is logical to assume that the establishment of differentiated framework directives would present added value and provide for a more effective patent regime. The framework directives would dictate the establishment of general patentability standards at the EU level but also allow national patent systems to set stricter standards for particular subject matters (i.e. for particular processes or products) based on the requirements of the local experts in the field. Such directives would enable the EU institutions to ensure that Member States are in line with the legislative requirements regarding patentability, and that the patentability provisions are not misused by countries to gain competitive advantages. In this way, the framework directives would lead toward structural convergence among the national systems in terms of patentability criteria and rules, the methodology used for assessing ‘an inventive step’, and the protection of new inventions. Moreover, when addressing sector-specific needs, the differentiated framework directives would enable national entities to set stricter standards for specific issues on top of the general EU level standards, and to align the degree of IP protection with the speed of technological development and the extent of market competition.

However, even though such a differentiated Community IP protection model might be an effective solution within the area of IP protection, it should be emphasized that, with the present industrial diversity, the Contracting States and other national IP stakeholders might fail to agree to follow the model at a uniform pace. The diversity in terms of economic development, technological expertise, and political power has always prevented national countries following uniform rules and principles, even when facing common challenges (Emmanouilidis, 2007). To avoid the risk of further impasses

²⁴ See: Paragraph 1A Sec. 4 of the German Patent Statute (PatG)

within the differentiated Community IP protection model, and to keep up with the dynamics of new technological developments (which see huge interdependences among cross-border innovations), it is important to investigate regulatory tactics that could co-opt experts from specific industries to shape and support knowledge generation and diffusion. Having seen that IP protection requires the collaboration of various stakeholders and experts, and embraces issues from various disciplines (such as law, economics, and technology), we argue that epistemic patent communities could be strong mechanisms for creating an inclusive patent-protecting environment that encourages the various IP actors to agree on certain principles that improve the quality of IPRs.

4.2. Epistemic Patent Communities - Toward a More Inclusive and Effective Patent Regime

Epistemic communities are considered to be groups constituted of various stakeholders and experts that have shared ways of knowing and patterns of reasoning. These groups work toward resolving policy projects by drawing on these shared beliefs, values and commitments to the production of knowledge. Epistemic communities differ from other groups in that they are knowledge-based communities consisting of experts from various disciplines with a strong ability to exert influence²⁵ and they very often act as soft bargaining instruments on behalf of Member States in reaching consensus on certain policy issues (Mani, 2006; Claes, Devroe and Keirsbilck, 2009). Epistemic communities have had pivotal roles in many fields, for example the Delors Committee²⁶ with its impact on European Monetary Union (EMU). Influenced mainly by monetary experts and central bankers, this Committee is considered as the most successful epistemic community in terms of its contribution to establishing the fundamentals of the single internal market and drafting the EMU's blueprint, which later formed the basis for the EMU articles within the Maastricht Treaty (Verdun, 1999). Similar to this example, epistemic communities could be established within the field of IP protection and form authoritative communities of professionals that would serve as the main bridge between the Contracting States, the European Parliament, and the European Commission. These

²⁵ Alder and Haas (1992) imply that four stages are crucial for epistemic communities: policy innovation, diffusion, selection, and persistence. First, epistemic communities need to frame the problem and determine the complexity of the issue area, which guides them in defining the stage for national and transnational interests in particular problems, and the level at which the problems should be solved. Next, the epistemic communities determine the mechanisms and the transnational links that the community members will use to make their views known, and to influence the preferences of other national governments (policy diffusion). Once the goals are set and the policy supporters are determined, the epistemic communities select those policies that have the most importance at the national level and seek their legitimization. *For more information see:* Adler, Emanuel & Peter M. Haas (1992). Conclusion: Epistemic Communities, World Order, and the Creation of a Reflective Research Program. *International Organization*, 46 (1), 367-390.

²⁶ Many national governments were against the dominance of the German Mark and of the Bundesbank in determining European Monetary policies, and thought that economic and monetary integration would benefit the European Community. Members of the Delors Committee shared the common beliefs that inflation was detrimental to growth and that stable exchange rates were necessary to ensure the proper operation of the Internal Market.

communities would assist the national and the EU institutions to overcome the many practical and technical barriers in various subject areas related to patentability.

In general, there are no widely accepted standards or specific processes for the regulation of policies that tackle innovation and technological developments (Mani, 2006). In Europe, many countries organize discussions and debates among stakeholders over the various components of the innovation system. There are various established forums (e.g. the Standing Advisory Committee before the EPO (SACEPO), the EUROTAB, and the European Patent Judges Symposium) which include legal professionals and technical experts that pool expertise and produce new knowledge on technical and legal matters (Borrás, 2006:10). However, these forums have failed to represent the interests of a wider range of stakeholders, or to encourage the establishment of well-defined initiatives. There appears to be a lack of effective participatory channels that can generate deliberative processes to enhance stakeholders' accountability.

Within the IP protection area, there is a need for more effective and well-organized communities consisting of patent attorneys, research institutions, administrators, lawyers, regular users of the patent system (i.e. companies), and other experts that have a crucial role in the exploitation, regulation, administration, and enforcement of the patent system (Dutfield, 2003; Claes, Devroe and Keirsbilck, 2009). Communities built upon these components would lead to strong epistemic patent communities and provide national governments with a body of experts with facts and arguments, derived from their professional collective work and knowledge on innovation, which could assist in making policy choices. Further, by virtue of their technical and scientific expertise, the actors in the epistemic patent communities will own complementary assets that could generate pro-IP values and establish an integrated IP regime. Such a bold move was taken within the biotechnology sector, where epistemic communities succeeded in protecting biotechnology inventions and making the existing IP protection regime allow for some degree of interpretative openness.

Even though the European Commission and the Council provide the impetus for an integrated patent regime, it is the establishment of epistemic patent communities that could enable effective outcomes. Unlike the above mentioned forums, these communities would provide incentives for the Contracting States and the European Parliament to get actively involved in discussions with well-informed stakeholders, would collect data that significantly inform decisions on the regulation of certain patentability subject matters, and would make useful proposals at the EU level. Epistemic patent communities would create an inclusive IP protection environment because various actors (both

national and regional, and including SMEs) will be encouraged to participate in policy dialogues that might move from draft proposals to regulations or, as Mani (2006: 3) puts it, from “green papers to white papers”. As such, the epistemic patent communities would weaken the divergent preferences of the Member States, encourage them to reach a consensus, support certain patentability standards, and establish a “small” patent community or union in which the granted patent will have a unitary character. Such an opportunity is included within the EPC provisions (particularly in Articles 142²⁷-149), which state that any group of Contracting States may join together and agree to accept granted European patents within their territories (Willems, 2002). Based on this, countries with similar IP protection interests can form a small patent community that would enable them to address these interests and establish the first steps toward an effective patent system. If the operations of this “small community” prove successful, this will attract other countries to join, and move toward creating a Community-wide patent protection regime.

5. Conclusions

This article highlights that the IP protection regulatory framework has, to a certain degree, been harmonized through the establishment of a centralized patent granting office that defines the general requirements for patentability at the European level, while leaving the implementation of IP standards to the national level. As a consequence, a fragmented patenting system has been initiated, in which the national patent systems are constrained by the supremacy of economic integration, the competition law, and the high levels of legal uncertainty. At the same time, the lack of an integrated European patent system and the failure of the long-term attempts to establish a Community patent regime have resulted in a failure to create an inclusive patenting environment, and this has hindered developments in technological and cumulative innovation activities. The current patent system is arguably in a state of crisis, having been challenged by the emergence of complex new technologies that build on cumulative innovation processes that have become the key factors in knowledge diffusion in many fields. Such complex ‘inventions’ (which are neither novel nor sufficiently inventive) have recently had a significant influence on the innovation and competition processes and have emphasized the need for EU legislation to move forward and adopt additional IP protection

²⁷ Unitary patents: Article 142 (1) reads “Any group of Contracting States, which has provided by a special agreement that a European patent granted for those States has a unitary character throughout their territories, may provide that a European patent may only be granted jointly in respect of all those States”. For more information see: http://www.regjeringen.no/upload/kilde/nhd/hdk/2006/0004/ddd/pdfv/285976-11epc2000_engelsk_text.pdf

schemes that would coordinate the distinct national IP protection rules and create legal frameworks that would encourage developments and implementation in the new industrial and electronic markets.

However, since neither the European nor the Community patent system has managed to deliver such a regime, the EU has moved toward establishing appropriate levels of sectoral IP protection through the application of the secondary EU law. These activities have successfully harmonized the patentability standards in certain sectors (especially in biotechnology), thereby emphasizing the impact that national IP stakeholders can have in tailoring the principles of the IP protection regime and in setting optimum levels of protection. Nevertheless, the EU activities to provide effective patentability frameworks in regards of new inventions have failed to fulfill the ambition of establishing an appropriate IP protection regime at the Community level. An appropriate IP protection regime is seen as one that would fulfill the requirements of the competitive innovation market and provide national and Community legislators with the opportunity to adopt the patent system to the needs of the market they control and to the industrial environment within which they operate.

Given the challenges and barriers to IP protection, as well as the inabilities of the existing regimes, we argue that effective IP protection, that would deliver patent quality and flexibility, could be achieved through the differentiated Community IP protection model. A model that combines framework differentiated directives with the activities of epistemic patent communities to provide a flexible solution that will have the character of the European law (in order to ensure a constitutional balance between the national patent systems and the rules of European economic integration) and will accommodate the existing diversity in innovation while coordinating the interactions of various stakeholders within the field. The application of this model would encourage the integration-minded industries and countries to move forward and advance certain developments in innovation. Moreover, this model might serve as a basis for the design of more-differentiated approaches that could be followed by several sectors (such as European social and welfare policies, defense, and healthcare) to regulate their policy issues at the Community level while overcoming the difficulties of simultaneously providing constitutional parity and preserving national diversity.

Overall, the differentiated Community IP protection model offers an effective alternative in the field of protecting IPRs, but much remains to be done. To ensure that the proposed model as outlined above is formulated and implemented successfully, policymakers will require detailed knowledge on the applicability of the Community IP protection model compared to the existing bilateral agreements

that some companies have started to employ (patent pooling, cross-licensing, etc). Even though these latter agreements are not regulated at the EU level, they do represent a differentiated form of collaboration that countries use to protect their inventions and to prevent litigation while acknowledging the patentability principles of other parties. As such, these agreements might be important factors that should be considered in any future research and when conducting further empirical analysis on IP protection issues.

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